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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
THOMAS, COURTNEY D	
ART UNIT	**PAPER NUMBER**
2882	

DATE MAILED: 02/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/942,528	LANG, PHILIPP	
	Examiner	Art Unit	
	Courtney Thomas	2882	

-- Th MAILING DATE of this communication appears on the cover she t with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 January 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,8-10 and 12-50* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,8-10,12-50* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1-4, 13-31 and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Inga et al. (U.S. Patent 5,384,643) in view of Ohkubo (U.S. Patent 6,449,502 B1).

4.

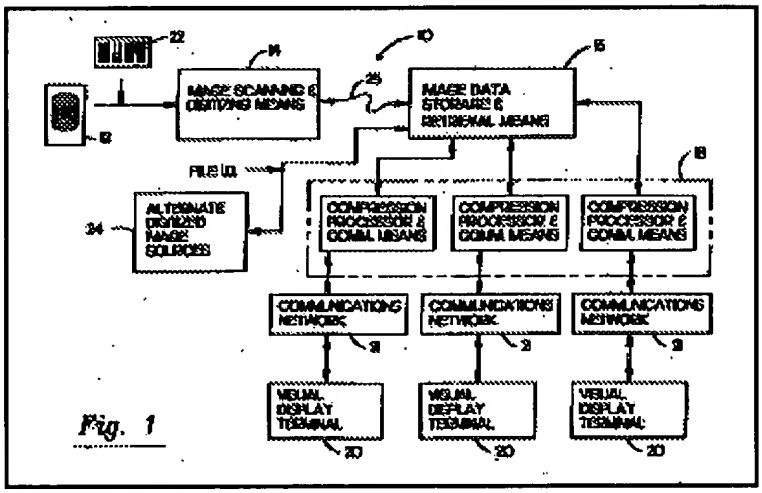


Fig. 1

5.

[57] **ABSTRACT**

A storage, retrieval, and transmission system is configured to provide fast, efficient telecommunication access to digitized images (e.g., medical diagnostic X-ray images) to multiple requesting subscribers. Image data are downloaded, via the telephone lines, to a remote display terminal in an optimal fashion that employs a two-dimensional patterned data compression scheme. The

Figure 1 and Abstract – U.S. Patent 5,384,643 to Inga et al.

6. **As per claims 1 and 48-50**, Inga et al. disclose a method comprising the steps of providing a **digitized X-ray image** on a local computer (abstract; column 6, lines 65-68, column 7, line 1); transmitting the X-ray image to a remote computer (abstract; column 7, lines 1-12) and analyzing the data at the remote computer. Inga et al. do not explicitly disclose a method comprising the step of deriving quantitative information on bone from the X-ray image at the remote computer.

7.

1. Field of the Invention

This invention relates to a bone measurement method and apparatus. This invention particularly relates to a method and apparatus for acquiring a quantitative index value, which represents a condition of a structure of a bone tissue of a human body, or the like, the condition being useful in making a diagnosis of osteoporosis, or the like, in accordance with a radiation image.

2. Description of the Prior Art

Bone mineral analysis, i.e., quantitative determination of amounts of calcium in bones, is useful for making a diagnosis for preventing fractures of bones.

Specifically, the amounts of the bone mineral are determined by the density of bone trabeculae, which are the cancellous matter constituting the internal regions of bones, i.e. the bone density. Therefore, if the bone density is low, the image density of a bone pattern in a bone image will become high. If the bone density is high, the image density of the bone pattern in the bone image will become low.

Therefore, by investigating small changes in the amounts of calcium contained in bones, osteoporosis can be found early, and fractures of the bones can be prevented.

Column 1, lines 5-27 - Ohkubo (U.S. Patent 6,449,502 B1)

8. Ohkubo teaches a method wherein quantitative information of bone is derived from a radiation image. Ohkubo teaches that a radiation image (including an X-ray image – column 1, lines 28-35) having bone attenuation data can be used to determine bone density by noting the density patterns appearing within the radiation image (see above). Ohkubo further teaches that analysis of radiation images and the determination of bone density assists in the identification of ailments such as osteoporosis and the prevention of bone fracture.

9. It would have been obvious to modify the method of Inga et al. such that it incorporated the step of determining quantitative information of bone from an X-ray image at a remote computer. One would have been motivated to make such a modification to determine bone density by noting the density patterns appearing within the radiation image and to determine from the image the presence of ailments such as osteoporosis as suggested by Ohkubo (column 1, lines 5-27).

10. **As per claim 2**, Inga et al. as modified, do not explicitly disclose a method wherein the analysis of the images comprises using a computer program on the remote computer.

11. It would have been obvious to further modify the method of Inga et al. such that it incorporated a remote computer configured with a program for analysis of images. One would have been motivated to make such a modification so that a remote computer could carry out automated analysis of received data, thereby providing near instantaneous results of program computations.

12. **As per claims 3-4**, Inga et al. as modified above, disclose a method wherein the quantitative information is densitometric information and wherein the densitometric information is bone mineral density.

13. **As per claims 13-17**, Inga et al. as modified above, do not explicitly disclose a method wherein x-ray acquisition parameters are transmitted to the remote computer; x-ray acquisition parameters are transmitted prior to, after or simultaneously with x-ray imaging; wherein x-ray acquisition parameters are selected from a group consisting of x-ray tube voltage, x-ray energy, x-ray tube current, film-focus distance, object-film distance, x-ray collimation, focal spot size, spatial resolution of the x-ray system, filter technique, and film-focus distance.

14. It would have been obvious to modify the method of Inga et al. such that it incorporated the aforementioned limitations. One would have been motivated to make such a modification so that acquisition parameters are correlated with obtained x-ray imagery, thereby enabling a practitioner to devise analyses of the correlated results and to set parameters that produce high quality images.

15. **As per claim 18-20**, Inga et al. as modified, do not explicitly disclose a method wherein the x-ray image further comprises one or more internal standards; the internal standard is density of a tissue of a human or air surrounding a structure and the internal standard is density of a tissue and the tissue is selected from the group consisting of subcutaneous fat, bone and muscle.

16. It would have been obvious to further modify the method of Inga et al., such that it incorporated x-ray images further comprising one or more internal standards representing the density of tissue of a human or air surrounding a structure; the tissue is selected from the group consisting of subcutaneous fat, bone and muscle. One would have been motivated to make such a modification so that areas of interest are easily recognizable within an image, thereby minimizing ambiguity amongst coexisting anatomical structures.

17. **As per claim 21**, Inga et al. as modified, do not explicitly disclose a method wherein the information is encrypted prior to transmission.

18. It would have been obvious to further modify the method of Inga et al. such that information is encrypted prior to transmission. One would have been motivated to make such a modification so that patient information is protected from unauthorized access during transmission via a network or mainframe; thereby preserving the integrity of personal information during transit.

19. **As per claims 22-26**, Inga et al. as modified, do not explicitly disclose a method comprising generating a diagnostic report based on the quantitative information; wherein the diagnostic report provides information on a patient's state of health; wherein the state of health is selected from the group consisting of bone mineral density status and fracture risk; further comprising generating a bill for the diagnostic report and wherein the bill is generated by a computer program on the remote computer.

20. It would have been obvious to further modify the method of Inga et al. such that it incorporated the aforementioned limitations. One would have been motivated to make such a modification so that obtained information is tabulated to reveal the state of a patient's health. Additionally, it would have been obvious to incorporate administrative documents such as billing information along with the generated diagnostic report. One would have been motivated to make such a modification so that services rendered is documented and provided along with a prognosis.

21. **As per claims 27-29**, Inga et al. as modified, disclose a method wherein the x-ray image is an x-ray film (**12**) and wherein the film is digitized using a scanning unit (**14**) (see Inga et al. - Figs. 1 and 2).

22. **As per claims 30 and 31**, Inga et al. as modified, do not explicitly disclose a method wherein an x-ray film image is digitally acquired using a selenium or silicon detector.

23. It would have been obvious to modify the method of Inga et al. such that an x-ray film is digitally acquired. One would have been motivated to make such a modification so that the additional step of converting an analogue image to a digital image is avoided, thereby reducing the complexity of an image data transmission process. Additionally, practitioners in the radiation art would be well aware of the use of selenium or silicon detectors for digital image acquisition; the selection of either of the aforementioned detectors would be at the discretion of a respective experimenter.

24. **As per claims 8-10 and 12**, Inga et al. as modified, do not explicitly disclose a method wherein quantitative information is information on the morphology of bone; the information based on two or three-dimensional arrangements of individual components forming the structure and wherein the structure is bone.

25. It would have been obvious to further modify the method of Inga et al. such that quantitative information is information on the morphology of a bone structure. One would have been motivated to make such a modification so that 2-D or 3-D images of bone structure could be used to determine whether a problem exists by comparing known structures to obtained images.

26. Claims 32-45 and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chiabrera et al. (U.S. Patent 5,917,877).

27.

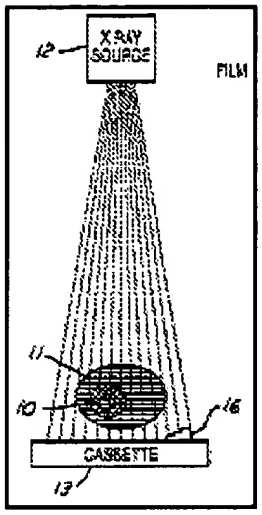


Figure 1 - U.S. Patent 5,917,877 to Chiabrera et al.

28. **As per claims 32, 39, 40 and 47**, Chiabrera et al. disclose an apparatus comprising an x-ray film holder (**13**), X-ray film ((**23**) - Fig. 2) a calibration phantom (**16**) and an x-ray imaging assembly and computer programs, wherein said computer programs analyze and assess bone mineral density (see Fig. 1 above and respective portions of the specification and included Figs.) Chiabrera et al. do not explicitly disclose a calibration phantom comprising a marker in an area of known density; the markers comprising a plurality of geometrical patterns.

29. Chiabrera et al. teach that a calibration phantom can comprise a wedge construction wherein differing heights represent varying thicknesses thereby allowing the distinct identification of wedge attenuating characteristics (column 3, lines 65 through column 4, line 3).

30. It would have been obvious to modify the apparatus of Chiabrera et al. such that it incorporated a calibration phantom comprising a marker in an area of known density. One would have been motivated to make such a modification so that the marker serves as a positioning

indicator for the phantom as well as an indicator for the attenuation attributes of the phantom at the indicated position as suggested by Chiabrera et al. Additionally, it is the position of the examiner that the patterning of the markers would not deviate from the scope and spirit of the disclosed invention.

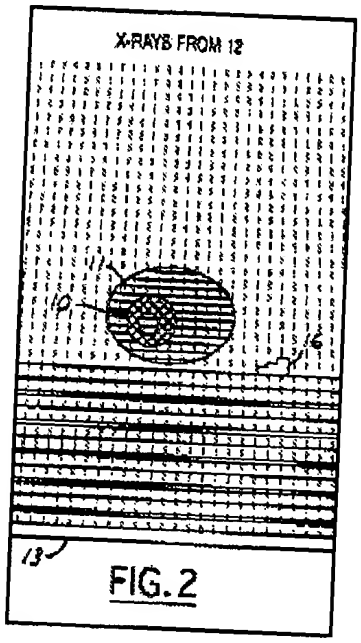
31. 

Figure 2 - U.S. Patent 5,917,877 to Chiabrera et al.

32. **As per claim 33**, Chiabrera et al. as modified, disclose an apparatus wherein the calibration phantom (**16**) projects free of bone tissue (Fig. 2, above).

33. **As per claim 34**, Chiabrera et al. as modified, disclose an apparatus wherein the calibration phantom is attached to the x-ray film holder or a detector system (Fig. 1, above).

34. **As per claim 35, 41, 42 and 43**, Chiabrera et al. as modified, disclose an apparatus wherein the calibration phantom is integral to the x-ray film holder included between two physical layers of x-ray film and included within one of the physical layers of the x-ray film (Figs. 1-3).

35. **As per claim 36 and 45**, Chiabrera et al. do not explicitly disclose an apparatus configured as a dental x-ray assembly and wherein the image is a dental x-ray image.

36. It would have been obvious to modify the apparatus of Chiabrera et al. such that it was configured as a dental x-ray assembly. One would have been motivated to make such a modification so that the assembly was configured for image capture and calibration of a particular portion of a patient's anatomy, such as patient's teeth and mandible structure.

37. **As per claim 37**, Chiabrera et al. as modified, disclose an apparatus wherein the calibration phantom comprises a step wedge (Fig. 4).

38. **As per claim 38,** Chiabrera et al. as modified, do not explicitly disclose an apparatus wherein the calibration phantom comprises a plurality of fluid-filled chambers.

39. It would have been obvious to modify the apparatus of Chiabrera et al., such that it incorporated a calibration phantom comprising a plurality of fluid-filled chambers. One would have been motivated to make such a modification so that the phantom would mimic the attenuation characteristics of soft tissue of a human body.

40. **As per claims 44**, Chiabrera et al. as modified, disclose a method comprising providing an assembly according to claim 32, wherein the calibration phantom is positioned such that x-rays pass through a subject and the calibration phantom simultaneously, wherein the calibration phantom projects free of materials that alter it's apparent density (see Fig. 2 above); creating an image of the phantom and the portion of the subject's anatomy; comparing the image of the phantom and the subject's anatomy to determine bone mineral density of the subject (abstract; columns 1-3, column 4, lines 1-41).

41. Claim 46 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chiabrera et al. (U.S. Patent 5,917,877) in view of Inga et al. (U.S. Patent 5,384,643).

42. **As per claim 46**, Chiabrera et al. do not explicitly disclose a method wherein comparing is performed in a network environment.

43. Inga et al. disclose a method wherein comparison is performed in a network environment (abstract; column 3, lines 17-45).

44. It would have been obvious to modify the method of Chiabrera et al. such that it incorporated the step of comparing performed in a network environment. One would have been motivated to make such a modification so that analysis could be accentuated by the ability to access several image and patient data from an archive source as taught by Inga et al. (abstract; column 3, lines 17-45).

Response to Arguments

45. Applicant's arguments filed 01.26.04 have been fully considered but they are not persuasive. In particular, Inga et al. (U.S. Patent 5,384,643) disclose a method comprising the steps of providing a digitized X-ray image on a local computer (abstract; column 6, lines 65-68, column 7, line 1); transmitting the X-ray image to a remote computer (abstract; column 7, lines 1-12) and analyzing the data at the remote computer. In addition to the above, Examiner additionally notes that Inga et al. teach the following:

46.

BACKGROUND OF THE INVENTION

Storage and retrieval systems for medical image data such as X-ray films, CAT scans, angiograms, tomograms and MRI are commonly antiquated. For example, when image films are used in the operating room, the physician must display these photo films on a light box.

Moreover, due to the diffuse responsibilities of multiple attending physicians and treatment sites, image data for patients with complex conditions is often lost, or at best, difficult to find when needed. Hospitals maintain large "file rooms" to store bulky patient image data films. In a complex situation in which several folders are needed, a file's weight can build up to 7 kg. It has proven time consuming to obtain image data from file rooms due to administrative backlogs, to lack of specialized filing personnel and to misfiling.

Typically, the physician examines the patient in his office after the radiographical studies have been made in a hospital or diagnostic facility. These films and the information contained therein are often unavailable at the time of the examination. Thus, there is a need for remote access to these image data for rapid patient assessment and therapy recommendation.

Column 1, lines 10-32 - U.S. Patent 5,384,643 to Inga et al.

47. As noted above, Inga et al. teach the impetus behind storage and retrieval systems for **medical image data** originates from the many responsibilities of multiple attending physicians and treatment sites wherein image data for patients with complex conditions is lost or unavailable when needed (see above column 1, lines 16-19). Inga et al. do not explicitly disclose the type of information to be obtained from the medical image data, but it is taught that from this information, a patient's condition can be assessed and a therapeutic program can be recommended (see above, column 1, lines 30-32).

48. Secondary reference to Ohkubo (U.S. Patent 6,449,502 B1) has been applied to the teachings of Inga et al. to meet the limitations as set by applicants' amendment. Ohkubo is

particularly relevant in the handling of radiation images comprising bone, since it is taught that bone density information can be obtained from the images by noting attenuation differences. Ohbuko further teaches that analysis of radiation images and the determination of bone density assists in the identification of ailments such as osteoporosis and leads to the prevention of bone fracture due to early detection. Examiner notes, that the term radiation image as used by Ohbuko also encompasses X-ray radiation images (see Ohkubo - column 1, lines 28-35).

49. Examiner concludes that medical practitioners would immediately recognize the benefit of the teachings of Inga et al. and Ohbuko to devise a system wherein radiation images are assessed for a particular medical assessment of a patient, such as deriving quantitive information of bone from a radiation image at a remote location.

50. With regards to claims 32-45 and 47, Examiner notes that independent claims 32 and 40 read: "... a calibration phantom comprising at least one marker positioned in an area of known density." Examiner has interpreted the claim as being drawn to a calibration phantom ... having a marker - placed in an area of the phantom, where the area of the phantom has a known density. As noted above, Examiner cites Chiabrera et al. (U.S. Patent 5,917,877). Chiabrera et al. teach that a calibration phantom can comprise a wedge construction wherein differing heights represent varying thicknesses thereby allowing the distinct identification of wedge attenuating characteristics (column 3, lines 65 through column 4, line 3). Based on the teachings of the construction of the Chiabrera et al. phantom, Examiner concludes that it would have been obvious to modify the calibration phantom such that it incorporated a marker in a known density area of the phantom. One would have been motivated to make such a modification so that the

marker serves as a positioning indicator for the phantom as well as an indicator for the attenuation attributes of the phantom at the indicated position.

Conclusion

51. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Courtney Thomas whose telephone number is (571) 272-2496. The examiner can normally be reached on M - F (9 am - 5 pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ed Glick can be reached on (571) 272 2490. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CT
Courtney Thomas

EDWARD J. GLICK
SUPERVISORY PATENT EXAMINER